

# MEDICAL PRODUCTS MFG. LLC.

## SPECIAL 510K

### 510(k) Summary

#### HLR™ Model-601 Heart Lung Resuscitator and HeartSaver 100

##### 1. SPONSOR

Medical Products Mfg., LLC.  
6 Thacher Lane  
Wareham, MA 02571  
508-291-1830

SEP 22 2006

Contact: John R. Driscoll, General Manager

Date Prepared: July 24, 2006

##### 2. DEVICE NAME

Proprietary Name: HLR™ Model-601 and HeartSaver 100  
Common/Usual Name: Heart-lung resuscitator  
Classification Name: Unclassified

##### 3. PREDICATE DEVICES

Pre-Amendment HLR® PARA-MED™ Heart Lung Resuscitator

##### 4. DEVICE DESCRIPTION

HLR Model-601 Heart Lung Resuscitator and the HeartSaver 100 are modifications to the pre-Amendment HLR® PARA-MED™ Heart Lung Resuscitator. The HLR Model-601 Heart Lung Resuscitator and the HeartSaver 100 are compact, totally portable, automatic CPR Devices. The HLR Model-601 and the HeartSaver 100 are air-powered medical devices used for emergency resuscitation of patients who have stopped spontaneous breathing. The HLR Model-601 and the HeartSaver 100 provide automatic chest compressions and ventilation per the current American Heart Association Guidelines. The devices can control the depth of chest compressions and the volume of ventilation. The HLR Model-601 and the HeartSaver 100 allow the trained user three options of compression to ventilation ratios (30:2), (15:2) and continuous chest compressions without ventilation.

<b>MEDICAL PRODUCTS MFG. LLC.</b>
<b>SPECIAL 510K</b>

**5. INTENDED USE**

The HLR Model-601 Heart Lung Resuscitator and the HeartSaver 100 are intended to be used as adjuncts to manual CPR on patients in cardiac arrest. The HLR Model-601 and the HeartSaver 100 are designed for use on adults or large children and should be administered by trained medical personnel.

**6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE**

The HLR Model-601 and the HeartSaver 100 are substantially equivalent to the parent device for intended use and indications for use as well as the basic overall functions.

**7. PERFORMANCE TESTING**

Verification and validation testing demonstrated that the modified devices, the HLR Model-601 and the HeartSaver 100 conform to design and performance specifications.



## DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP 22 2006

Medical Products Manufacturing, LLC  
c/o Mr. John R. Driscoll  
General Manager  
6 Thacher Lane  
Wareham, MA 02571

Re: K062119  
HLR™ Model 601 Heart Lung Resuscitator and Heartsaver 100  
Regulation Number: 21 CFR 870.5200  
Regulation Name: External Cardiac Compressor  
Regulatory Class: Class II (two)  
Product Code: DRM  
Dated: September 14, 2006  
Received: September 15, 2006

Dear Mr. Driscoll:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2 – Mr. John R. Driscoll

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

*Bram D. Zuckerman*

*BM*

Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

# MEDICAL PRODUCTS MFG. LLC.

## SPECIAL 510K

510(k) Number (if known):

*K062119*

Device Name: HLR™ Model-601 Heart Lung Resuscitator and HeartSaver 100

### Indications For Use:

The HLR™ Model-601 Heart Lung Resuscitator and the HeartSaver 100 are intended for use as adjuncts to manual CPR on patients who are non-breathing, unconscious, pulseless and in urgent need of cardiopulmonary resuscitation.

Prescription Use   
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use   
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Dawn R. Vachner*  
(Division Sign-Off)  
Division of Cardiovascular Devices

510(k) Number *K062119*